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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/405,050	09/27/1999	YEHUDA SHOENFELD	ZAP-1CIPCONC	9070

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EXAMINER

NAVARRO, ALBERT MARK

ART UNIT

PAPER NUMBER

1645

DATE MAILED: 01/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

09/405,050

Applicant(s)

SHOENFELD ET AL.

Examiner

Mark Navarro

Art Unit

1645

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 08 December 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☒ The period for reply expires 5 months from the mailing date of the final rejection.
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
(a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ they raise the issue of new matter (see Note below);
(c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____

3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See attached.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☐ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____

Claim(s) objected to: _____

Claim(s) rejected: _____

Claim(s) withdrawn from consideration: _____

8. ☐ The drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
10. ☐ Other: _____

ADVISORY ACTION

Applicants responses filed November 9, 2004 and December 8, 2004 have been received and entered. Accordingly claims 1-11 and 22-29 remain pending in the instant application.

Claim Rejections - 35 USC § 112

1. The rejection of claims 1-11 and 22-29 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, a new matter rejection is maintained.

Applicants are asserting that Applicants provide support for treating metastasis, and lymphoma is specifically relevant in this context as a cancer. (Page 7, lines 11-13 and 15-20). Applicants further assert that Examples 1-5 demonstrate a direct effect of IVIG in inhibiting metastasis of two different cancers, a carcinoma and a sarcoma, establishing therefore, support for treating cancer metastasis, as a general principle, with IVIG. Applicants further assert that as set forth in MPEP 2164.02, that sufficient support for a claimed genus (treatment of cancer metastasis with IVIG) exists, since the Specification contains representative examples together with a statement applicable to the genus as a whole (Page 1, lines 2-4 and page 3, lines 15-17 and 19). Applicants further point toward Example 8, which demonstrates that lymphoma cells are

responsive to IVIG, inhibiting cell proliferation, providing further support for the applicability of the instant invention, that of preventing metastasis, to lymphoma.

Applicants arguments have been fully considered but are not found to be fully persuasive.

First, Applicants assert that the specification provides support for treating metastasis, and lymphoma is specifically relevant in this context as a cancer. (Page 7, lines 11-13 and 15-20). However, the specification sets forth that frequently, "metastasis of tumor cells will occur as a result of the physical manipulation of the tumor during surgery." The claims recite that the inhibition must take place in a mammal which has "metastatic lymphoma." However, there is no guidance within this passage of the specification to specifically isolate a subgenus of individuals who have active metastasis from those who do not for treatment, let alone any mention pertaining specifically to lymphomas. Furthermore, carcinomas frequently undergo metastasis, where is the guidance to exclude these individuals while only including those who have metastatic lymphomas?

Second, Applicants assert that Examples 1-5 demonstrate a direct effect of IVIG in inhibiting metastasis of two different cancers, a carcinoma and a sarcoma, establishing therefore, support for treating cancer metastasis, as a general principle, with IVIG. However, Applicants are directed to their own arguments. They correctly recite that "One skilled in the art will readily recognize that cancerous cells that metastasize are phenotypically distinct from cells that remain at the primary tumor site." This phenotypical distinction is several fold more pronounced with different types of

cancers, lymphomas, to which the claims are directed versus carcinomas and sarcomas as set forth in the Examples.

Third, Applicants assert that as set forth in MPEP 2164.02, that sufficient support for a claimed genus (treatment of cancer metastasis with IVIG) exists, since the specification contains representative examples together with a statement applicable to the genus as a whole (Page 1, lines 2-4 and page 3, lines 15-17 and 19). However, Applicants claims are not directed to a genus, rather the claims are directed to treating a subpopulation, (i.e., only those who have current metastatic lymphoma). It is this limitation, selection of only those who have metastatic lymphoma, which is deemed to be new matter.

Finally, Applicants point toward Example 8, which demonstrates that lymphoma cells are responsive to IVIG, inhibiting cell proliferation, providing further support for the applicability of the instant invention, that of preventing metastasis, to lymphoma. However, Applicants will note that Example 8 was carried out *in vitro*. No determination was made nor could have possibly been made as to whether the lymphoma had metastasized.

For reasons of record, as well as the reasons set forth above, this rejection is maintained.

Double Patenting

2. The rejection of claims 1-11 and 22-29 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-18 of U.S. Patent No. 5,965,130 is maintained.

It is noted that Applicants have indicated a willingness to submit a terminal disclaimer upon an indication that all other rejections are withdrawn. However, until a terminal disclaimer is made of record, this rejection is maintained for reasons of record.

3. The rejection of claims 1-11 and 22-29 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 5,562,902 is maintained.


It is noted that Applicants have indicated a willingness to submit a terminal disclaimer upon an indication that all other rejections are withdrawn. However, until a terminal disclaimer is made of record, this rejection is maintained for reasons of record.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro whose telephone number is (571) 272-0861.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Mark Navarro
Primary Examiner
January 12, 2005